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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
WESTERN DIVISION

JUDITH D. WALLS, et al.,	]	
	]	
Plaintiff(s),	]	
	]	
vs.	]	CV-99-CO-02032-W
	]	
ALPHARMA USPD, INC., et al.,	]	
	]	
Defendant(s).	]	

Memorandum of Opinion

Plaintiff Brittany Adams claims she suffers from permanent injuries as a result of her mother's use of Alpharma's generic lindane 1% solution during pregnancy. *See* October 15, 2004, Memorandum of Opinion. (Doc. 150.) This court previously denied Alpharma's motion for summary judgment on all counts. (Doc. 150.) On November 16, 2004, Alpharma filed a "Request To Be Heard," which was treated as a motion for reconsideration. (Doc. 153.) The Court accepted additional briefing on the learned intermediary doctrine and causation. (Doc. 154.) The issues have been fully briefed and are ripe for review.

I. The Learned Intermediary Doctrine and Causation.

In its October 15, 2004, opinion, this Court observed that the adequacy of warnings is generally a question of fact which must be resolved by the fact-finder, citing *Toole v. McLintock*, 999 F.2d 1430, 1433 (11th Cir. 1993). Nevertheless, Alpharma contends that the learned intermediary doctrine permits this Court to determine the adequacy of warnings as a matter of law and asserts that "Alabama law provides summary judgment as an appropriate vehicle for resolving the adequacy of warnings in prescription drug cases." (Doc. 156, p. 4.) The Court has reviewed the cases cited by Alpharma and finds nothing therein to support this sweeping claim.[1] *Emody v. Medtronic, Inc.*, 238 F. Supp. 2d 1291, 1296 (N.D. Ala. 2003)(plaintiff

[1]Two of the cases cited by Alpharma do not relate to claims against manufacturers. *Sanks v. Parke-Davis, Inc.*, 2000 WL 33910097, *4 -5 (M.D.Ala. 2000)(pharmacy or pharmacist who correctly fills a prescription in strict accordance with the prescribing physician's directions is protected by the learned intermediary doctrine); *Lansdell v. American Home Products Corp.*, 1999 WL 33548541, *1 (N.D.Ala. 1999)(same). Two other cited cases involved claims that patients should have received direct warning, which is not an issue in this case. *Vitanza v. Upjohn Co.*, 778 A.2d 829 (Conn. 2001)(where adequate warnings were provided to physician, learned intermediary doctrine precluded plaintiff's claim that consumer should be directly warned about risk of fatal allergic reaction on promotional samples distributed only through a physician); *Presto v. Sandoz Pharmaceuticals Corp.*, 487 S.E.2d 70 (Ga. App. 1998)(affirming summary judgment for drug manufacturer because manufacturer had no duty to directly warn patient of danger in abruptly discontinuing drug).

failed to raise a genuine dispute of material fact concerning adequacy of warnings where package insert for broken medical device contained warnings concerning the risk of breakage and treating physician testified he chose not to follow manufacturer's removal warning); *Morguson v. 3M Company*, 857 So. 2d 796 (Ala. 2003)(warnings given by manufacturer cautioned against exact acts and omissions of hospital employees); *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254 (5th Cir. 2002)(applying Louisiana law, plaintiff failed to raise a genuine issue of material fact and warning was adequate as a matter of law where (1) he claimed the warning failed to warn physician of risks of liver dysfunction and cholestatic hepatitis but label mentioned disorders and prescribing physician unequivocally testified warning was adequate to inform him of those risks involved in prescribing the drug; (2) he claimed the warning failed to warn physician of possible liver failure and death but these risks were obvious to physician warned of liver dysfunction and (3) he claimed the warning recommending medical monitoring was inadequate but expert testimony advocating earlier testing did not create material question of fact as to whether instructions enabled physician to use the drug safely); *Hall v. Sinn, Inc.*, 102 Fed. Appx.

846, 2004 WL 1418787 (5th Cir. 2004)(applying Louisiana law, summary judgment affirmed where plaintiff's claim was subject to issue preclusion and plaintiff offered no expert testimony that warning was inadequate and no evidence of causation since prescribing physician testified he did not read warning but knew of risks attendant to use of drug); *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013 (8th Cir. 2003)(applying North Dakota law, summary judgment affirmed where prescribing physician was aware that psychosis was a possible side effect of medication); *Plummer v. Lederle Laboratories*, 819 F.2d 349 (2d Cir. 1987)(applying California law, jury verdict for plaintiff vacated because warning adequately informed prescribing physician that live polio virus vaccine could cause paralytic disease in unvaccinated persons having contact with vaccinee and law did not impose a duty on manufacturer to advise precautions in warning and prescribing physician had independent knowledge of risks and precautions advocated by plaintiff so that their absence from warning could not be proximate cause of plaintiff's injuries); *Hunt v. Hoffman-La Roche, Inc.*, 783 F. Supp. 547 (D. Maryland 1992)(applying Maryland law, summary judgment granted because prescribing physician and patient testified to knowledge of

risk to unborn baby and knew that Accutane must not be taken when pregnant; manufacturer did not have to require pregnancy test prior to prescribing drug because physician was learned intermediary); *Thomas v. Hoffman-La Roche, Inc.*, 949 F.2d 806 (5th Cir. 1992)(applying Mississippi law, affirming judgment notwithstanding the verdict for manufacturer, distinguishing *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974) because Texas courts had adopted a presumption of causation for products with avoidable risk, but not for products with unavoidable risk and, therefore, plaintiff must present some evidence that warning advocated would have changed physician's decision to prescribe Accutane for plaintiff, and no evidence showed that warning of seizure risk would have changed prescribing physician's decision). These cases merely highlight the Court's previous conclusion that the adequacy of a warning is a question of fact which can be resolved on summary judgment only when there is no dispute of material fact.

The PDR warning for lindane is not adequate as a matter of undisputed fact. The Alabama case Alpharma cites is instructive on that question. In *Morguson v. 3M Company*, 857 So. 2d 796 (2003), the Alabama Supreme

Court affirmed summary judgment for the manufacturer of one component of a heart-lung machine which malfunctioned during heart by-pass surgery, stating that "[t]he warnings given by Baxter in this case cautioned against the exact acts and errors committed by DCH employees." *Id.* at 802. Adams contends the PDR warning about lindane did not adequately warn prescribing physicians about a heightened potential for harm to an exposed fetus. The warning advised the drug should be used "with caution" on infants, children and pregnant women. As discussed in its October 15, 2004, Memorandum of Opinion, given the expert testimony in the record that the direction is vague, this Court cannot say that the PDR warning is adequate as a matter of undisputed fact.[2]

[2]In *Tatum v. Schering Plough*, the plaintiff claimed, *inter alia*, that the warning did not accurately convey the degree of risk in using gold therapy to treat rheumatoid arthritis, and that the physician or the patient may have chosen a different treatment if they had known the actual risk. 795 F.2d at 927-28. The Court pointed to expert testimony that the use of the word "rare" to describe the incidence of adverse reactions was weak. *Id.* This Court recognizes that the defendant has filed motions in limine arguing that much of Plaintiff's expert testimony should be excluded pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). However, those motions are not yet resolved and the expert testimony of Dr. Rasmussen, discussed here and in this Court's October 15, 2004, Memorandum of Opinion, is not challenged in those motions.

Nevertheless, Alpharma argues that, even if its warning was inadequate it is entitled to summary judgment because Dr. Lucy, the prescribing physician, had independent knowledge of the alleged hazards of lindane.[3] It is apparent from the cases cited by Alpharma that causation is lacking when the physician's independent knowledge encompasses the very information the plaintiff claims should have been included in the warning.[4]

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[3]In *Tatum*, the Eleventh Circuit, applying Alabama law, said the treating physician's independent knowledge that there was no universally accepted treatment for aplastic anemia barred a conclusion of proximate causation with respect to plaintiff's claim that the warning on the drug at issue should have stated that treatments for adverse reactions to gold therapy had not been proved to be of value or were controversial. 795 F.2d at 928.

[4]*Emody v. Medtronic, Inc.*, 238 F. Supp. 2d 1291 (N.D. Ala. 2003)(package insert contained adequate warnings concerning the risk of breakage and warning was not cause of plaintiff's injury where treating physician testified that his knowledge came from medical books, journals, newsletters, meetings, and peer discussions and he did not even read the package insert provided by manufacturer and chose not to follow removal instructions); *Hall v. Sinn, Inc.*, 102 Fed. Appx. 846, 2004 WL 1418787 (5th Cir. 2004)(warning played no role in events leading to plaintiff's injury where prescribing physician testified he did not read warning but knew of risks attendant to use of drug); *Muller v. Synthes*, 2002 WL 460827, *10 (N.D. Ill.)(summary judgment granted where plaintiff complained implant broke and treating physician denied ever reading manufacturer's inserts and testified he warned plaintiff about possible failure of the instrumentation showing he knew generally of the risk that devices implanted in the body might fail); *Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272 (11th Cir. 2002)(applying Georgia law, affirming summary judgment for manufacturer of patient-controlled morphine pump as to plaintiff's claim that pump should have had label warning of danger when person other than patient activated device; where danger was generally known in the medical community and manufacturer adequately warned hospital's physicians and nurses of alleged danger, manufacturer had no duty to warn patient and family directly).

Dr. Lucy, the treating physician in this case, testified she was familiar with the PDR information about lindane. As discussed above, the PDR warning did not provide the information about special risks to an exposed fetus that plaintiff claims should have been included. In view of the expert testimony that the directions for treating pregnant women "with caution" was vague, there is support for plaintiff's claim that the treatment might have been different if such information was included. Therefore, the plaintiff has sufficient evidence of causation to go to a jury unless the defendant can show that the information missing from the warning was encompassed within Dr. Lucy's independent knowledge.[5]

Alpharma argues Dr. Lucy had sufficient information about lindane, pointing to Dr. Lucy's testimony that she learned about lindane during her residency training at UAB, and that during her residency she treated children

[5]In *Tatum*, the Eleventh Circuit held that material questions of fact made it incorrect to hold by summary judgment that proximate cause did not exist as to plaintiff's evidence that the manufacturer should have warned the physician about the level of risk for aplastic anemia and should have instructed the physician to establish a baseline of blood values for comparison. 795 F.2d at 928. Further, the Court said questions of fact made it incorrect to find there was no proximate causation as to the plaintiff's contention that the manufacturer should have sent a letter to physicians notifying them of the drug's changed warning pursuant to the FDA's "boxed warning" requirement. *Id.* at 927-28. As to these arguments, the Court said there was no evidence in the record of the physician's independent knowledge.

and pregnant women the same way she treated Mrs. Walls. (Doc. 156, p. 9, citing Dr. Lucy's deposition at pp. 39-40, 76.)[6] Alpharma also argues that Dr. Lucy's treatment of Mrs. Walls, prescribing two applications of Eurax and an application of six percent sulfur prior to trying lindane, was evidence she "appreciated the caution to be used" when prescribing lindane for pregnant women. (Doc. 156, p. 14.) Dr. Lucy instructed Ms. Walls to apply the lindane from chin to toes, covering all areas, and leave it on less than eight hours before washing it off. (Doc. 156, p. 15, citing Dr. Lucy's deposition at pp. 29-30.) Alpharma also argues that Dr. Lucy knew many things about lindane, such as: (1) it is absorbed through the skin and into the bloodstream of humans; (2) it is more easily absorbed through damaged skin; (3) certain things, such as wet skin or warm skin or oils or creams, can increase the absorption rate. (Doc. 156, p. 17, citations to Lucy deposition omitted.) Dr. Lucy testified she knew of a few adverse reactions that had been reported, stating "[w]hat adverse reactions were almost unheard of unless the patient had misused the medicine [sic]. But with repeated applications and with

[6]Unless otherwise noted, the cited excerpts from Dr. Lucy's deposition are in D. 157, Defendant's Evidence, Tab A.

ingestion of medicine, seizures had occurred in some people." (Doc. 156, p. 17, citing Dr. Lucy's deposition at pp. 40-41.) Dr. Lucy testified that she did not believe lindane was toxic if properly used, and that "young children were safely treated with lindane as long as they were treated the way the medicine was prescribed; if it was prescribed accurately and correctly . . . ." (Doc. 156, p. 19, citing Dr. Lucy's deposition at pp. 24-25, 53.) Dr. Lucy said, "[t]he risk would be almost nothing. As long as she did it as it was prescribed, the risk would be just about nothing, but the benefit would be that it's a very effective treatment for scabies." (Doc. 156, p. 20, citing Dr. Lucy's deposition at p. 31.) This cited testimony does not show that Dr. Lucy knew lindane might cause permanent damage to an exposed fetus as claimed by the plaintiff and her experts. Rather, Dr. Lucy testified she believed the worst possible effect would be seizures caused by misuse or ingestion. Further, although the warning said to "use with caution" in children, infants and pregnant women, Dr. Lucy testified she treated children like adults and that pregnant women should not get more than one

application,[7] but her treatment of Ms. Walls also indicates she used lindane as a third choice. The evidence tends to support the plaintiff's contention that the "use with caution" direction was vague. The plaintiff also disputes Dr. Lucy's belief that no adverse effects would occur if the lindane were used properly. Certainly, the Court can't say that Dr. Lucy's independent knowledge encompassed the very information the plaintiff claims should have been included in the warning.

Alpharma contends this case is strikingly similar to *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806 (5th Cir. 1992)(applying Mississippi law) where the plaintiff complained that Accutane had caused her seizures and the treating physician testified he was aware of the possibility of seizures and had weighed the benefits and risks prior to prescribing the drug. (Doc. 156, p. 23.) However, the Fifth Circuit's decision to affirm the JNOV for the defendant manufacturer in *Thomas* was not based on the

[7] Dr. Lucy testified that she treated children and adults the same, by having them apply lindane overnight and wash in the morning. (Doc. 156, p. 9, citing Dr. Lucy's deposition at pp. 42, 68, 76.) As to treatment of pregnant women, she said "[a]gain, just the use with caution and not repeated uses." *Id.* She testified "with pregnancy and with lindane, we always use - we use anything with caution when people are pregnant, and the same thing would go with lindane, that you use it just as it's prescribed; you don't use it any other way." (Doc. 156, p. 9, citing Dr. Lucy's deposition at pp. 42, 68, 76.)

treating physician's independent knowledge. Rather, the Court found that, although it had previously held that Texas courts would presume causation if a warning was inadequate, under Mississippi law the plaintiff had the burden of showing that an adequate warning would have changed the treating physician's decision to prescribe Accutane in addition to showing the drug caused her injury. *Id.* at 811-814. The Fifth Circuit concluded:

> We hold that [the] undisputed historical evidence concerning the [undiminished] usage of Accutane after an adequate seizure warning was given precludes any reasonable possibility that information on the ten reported seizures would have prevented [Plaintiff's] injury. The possibility that Dr. Myers would have changed his decision is too remote to create a genuine issue of fact with respect to warning causation.

Id. at 817. Defendant has made no attempt to show that Alabama would apply the Mississippi rule as applied by the Fifth Circuit. Further, the *Thomas* plaintiff claimed her seizures were caused by Accutane and that the warning should have mentioned the risk of seizures, but her treating physician was aware of the seizure risk. Therefore, his independent knowledge encompassed the very information the plaintiff claimed should have been in the warning. In contrast, there is no evidence that Dr. Lucy had independent knowledge that lindane could cause damage to an exposed

fetus's central nervous system, as plaintiff claims. Rather, as discussed above, Dr. Lucy testified that she heard of possible seizures if the drug was misused or ingested. Therefore, *Thomas* is inapposite.[8]

II. Additional Arguments.

Citing *Needleman v. Pfizer, Inc.*, 2004 WL 177369 (N.D. Tex. Aug. 6, 2004),[9] Alpharma argues that the plaintiff's inadequate warning claim is preempted by federal law because

> [t]he FDA already had addressed that issue by the time that Dr. Lucy prescribed lindane for Mrs. Walls and did not find that the scientific evidence was sufficient to warrant a labeling change. Beginning in 1983, the FDA Dermatologic Advisory Committee conducted meetings that addressed, among other things, whether lindane labeling should be changed to warn against the use of lindane in pregnant women. . . . The FDA concluded that lindane could still be prescribed for pregnant women. . . .

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[8]The *Thomas* Court also questioned whether the plaintiff had actually proved her seizures were caused by Accutane. That issue is not before this court in these summary judgment proceedings.

[9]Alpharma also cited *Mottlus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004) in support of its argument that the FDCA and FDA regulations preempt the plaintiffs claims. In *Mottlus*, the plaintiff claimed Pfizer should have warned of a link between its drug, Zoloft, and suicide. *Mottus* is inapposite because, although the FDA submitted an *amicus* brief arguing that the plaintiff's inadequate warning claim was preempted by FDA findings that SSRI's and suicide were not linked, the Ninth Circuit affirmed summary judgment for Pfizer based on evidence that the prescribing physician had not read the warning, so that the plaintiff could not show her husband's suicide was caused by the warning.

(Doc. 156, at 28 (citing Report of Bob Pollack, Doc. 157, Tab 3 at 13).) This Court does not find *Needleman* persuasive. Most federal courts appear to be in agreement that the Food Drug and Cosmetic Act does not preempt state product liability claims based on allegedly inadequate warnings for prescription drugs. *See, e.g., Medtronics v. Lohr*, 518 U.S. 470 (1996)(preemption provision of Medical Device Amendment to FDCA does not preempt state common law claims for defective design, labeling and manufacturing); *Hill v. Searle Labs.*, 884 F.2d 1064 (8th Cir. 1989) (FDA's approval of intrauterine device did not shield manufacturer from liability for state claims, FDA regulations are generally minimal standards of conduct); Abbott *v. American Cyanamid Co.*, 844 F.2d 1108 (4th Cir. 1988)(although vaccine production was extensively regulated, the FDCA did not impliedly preempt state tort claim); *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir. 1981)(rejecting argument of manufacturer of oral contraceptive that warning was adequate because FDA prescribed language). *And see Globetti v. Sandoz Pharmaceutical Corp.*, 2001 WL 419160 (N.D. Ala. 2001)(Putnam, M.J.)(plaintiff's claim that FDA-approved package insert did not adequately warn of risks associated with use of Parlodel for suppression

of post-partum lactation). Furthermore, the *Needleman* Court relied on a report that the FDA had determined that warning of an increased risk of suicide with the use of Zoloft would be false, misleading and harmful to patients. In contrast, Alpharma's expert stated only that an FDA committee considered "the need to add additional warnings with respect to toxicity in pregnant women and premature infants" in October 1983, and that unspecified changes in the labeling were made at an unspecified later date based on the recommendation of the committee. (Pollack Report, Doc. 157, Tab 3 at 13.) There is nothing to show the FDA's actions conflicted with the plaintiff's position.

Finally, Alpharma argues the plaintiff's negligence claims are subsumed by the AEMLD. Alpharma previously relied on *Spain v. Brown & Williamson Tobacco Corp.*, 230 F.3d 1300 (M.D. Ala. 2001), but this Court observed in its October 15, 2004, Memorandum of Opinion that the Alabama Supreme Court ultimately concluded the negligence claims in *Spain* were not subsumed by AEMLD. *Spain v. Brown & Williamson Tobacco Corp.*, 872 So. 2d 101 (Ala. 2003)(response to question certified by Eleventh Circuit). Now, Alpharma argues *Spain* is inapposite because the AEMLD claims there

were based on a defective product and so the *Spain* plaintiff could conceivably bring a separate common-law claim for defective warning. Here, Alpharma urges, the negligence claim is subsumed by the AEMLD because a plaintiff complaining about an unavoidably unsafe prescription drug has only one viable claim, for defective warning. Nothing in *Spain* supports this reasoning. It does not appear that the *Spain* plaintiff's negligence claims were different from his AEMLD claims. Further, the Alabama Supreme Court did not base its conclusion on an assumption that the plaintiff was bringing two different claims. Rather, the Court said: "[w]e cannot deduce from this Court's announcement of the AEMLD in *Casrell*[10] that the common law was thereby abrogated by negative inference. . . . Spain's negligence and wantonness claims are . . . viable alternatives to his AEMLD claim."

III. Conclusion.

For the reasons set forth herein, Alpharma's "Request To Be Heard," which was treated as a motion for reconsideration, will be denied by separate order.

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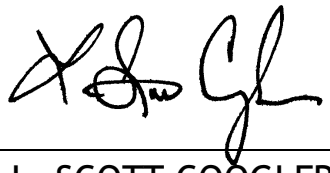
[10]*Casrell v. Altec Industries, Inc.*, 335 So. 2d 128 (Ala. 1976).

Done this 10th day of March 2005.



L. SCOTT COOGLER
UNITED STATES DISTRICT JUDGE
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